



U.S. ENVIRONMENTAL PROTECTION AGENCY
 Office of Pesticide Programs
 Biopesticides and Pollution Prevention Division (7511P)
 1200 Pennsylvania Avenue NW
 Washington, DC 20460

NOTICE OF PESTICIDE REGISTRATION

Registration
 Reregistration

(under FIFRA, as amended)

EPA Reg. Number:
524-575

Date of Issuance:
 6/10/08

Term of Issuance:

**Conditional
 Time-Limited**

Name of Pesticide Product:

MON 89034

Name and Address of Registrant (include ZIP Code):

Monşanto Company
 800 North Lindbergh Blvd.
 St. Louis, MO 63167

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

The registration application referred to above, submitted in connection with registration under ' 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided that you do the following terms and conditions.

- 1) The subject registration will automatically expire on midnight September 30, 2010.
- 2) The subject registration will be limited to MON 89034 in field or sweet corn. Further, MON 89034 sweet corn may only be sold directly to processors or through commercial dealers to large growers. MON 89034 sweet corn may not be sold to small roadside or home growers
- 3) Submit/cite all data required for registration of your product under FIFRA §3(c)(5) when the Agency requires registrants of similar products to submit such data.

Signature of Approving Official:

See last page JAH
 Janet Andersen, Ph.D., Director

Date:

6/10/08

Biopesticides and Pollution Prevention Division (7511P)

SYMBOL	EPA Form 8570-6	Bill	7511P				
SURNAME		Scovill	mon				
DATE		6/10/08	6/10/08				

4) Submit the following data in the time frames listed:

OPPTS Guideline/ Study Type	Required Data	Due Date
860.1340 Residue Analytical method - Plants	For event MON 89034 corn, an independent lab validation of the analytical method for the detection of Cry2Ab2 and/or Cry1A.105. The registrant must also agree to provide to the EPA laboratory (Ft. Meade, MD) methodology and/or reagents necessary for validation of such analytical method within 6 months from the date that the Agency requests them.	4/1/2009
850.1010 Aquatic Invertebrate Acute Toxicity Testing, Freshwater <i>Daphnids</i>	A 7 to 14 day <i>Daphnia</i> study as per the 885 Series OPPTS Guidelines needs to be performed. Alternatively, a dietary study of the effects on an aquatic invertebrate, representing the functional group of a leaf shredder in headwater streams, can be performed and submitted in lieu of the <i>Daphnia</i> study.	4/1/2009
Insect Resistance Management	Monsanto did not address the likelihood of cross-resistance of Cry1A.105, Cry1Ac, Cry1Fa, proteins already in existing Bt corn and Bt cotton products, and what impact such cross-resistance would have on the durability of MON 89034. Monsanto must provide additional information on cross-resistance of Cry1A.105 and Cry1Fa and Cry1Ac (preferably including binding site models and use of resistant colonies) for the target pests and determine how such cross-resistance may impact the durability of MON 89034. The Cry1A.105 protein is a chimeric protein consisting of Domains I and II and the C-terminus of Cry1Ac and Domain III of Cry1Fa. It is important to address not only the likelihood of cross-resistance potential of Cry1A.105 and Cry1Ab and, similarly, Cry1A.105 and Cry2Ab2 (which was done by Monsanto), but also that of Cry1A.105 and Cry1Ac and Cry1Fa.	4/1/2009 Protocol Due 8/1/2008
Insect Resistance Management	Monsanto did not sufficiently address the cross-resistance of Cry1A.105, Cry1Fa, and Cry1Ac in the cotton-growing landscape and how cross-resistance may impact the durability of MON 89034. Should cross-resistance be of concern then the durability of MON 89034 in the southern cotton-growing areas might be compromised. Monsanto needs to address this issue in subsequent simulation modeling.	4/1/2009 Protocol Due 8/1/2008
Insect Resistance Management	Baseline susceptibility studies and/or a discriminating concentration assay are required for the Cry1A.105 protein against ECB, SWCB, and CEW and for the Cry2Ab2 protein against SWCB, CEW.	4/1/2009

OPPTS Guideline/ Study Type	Required Data	Due Date
Insect Resistance Management	To support sweet corn uses, baseline susceptibility studies must be conducted on FAW populations collected from sweet corn growing areas. Monitoring studies will be conducted on FAW populations collected from sweet corn distribution areas in states in which Monsanto MON 89034 and/or MON 89034 x MON 88017 sweet corn plantings exceed 1000 acres. The collected populations of FAW will be monitored for changes in susceptibility to the Cry1A.105 and Cry2Ab2 proteins.	4/1/2010

5) The registrant must do the following Insect Resistance Management Program for MON 89034.

a) Refuge Requirements for MON 89034.

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn nor to commercial hybrid sweet corn.

Grower agreements (also known as stewardship agreements) will specify that growers must adhere to the following refuge requirements or, in the case of sweet corn, harvest practices as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

For MON 89034 sweet corn, growers are required to destroy any MON 89034 sweet corn stalks that remain in the field following harvest via rotary mowing, discing, or plow-down within one (1) month of harvest.

The corn borer refuge must be planted with a non-Bt/lepidopteran-protected hybrid, must represent at least 20% of the grower's corn acres (i.e. sum of [MON 89034] acres and corn borer refuge acres), and must be planted within ½ mile of the [MON 89034] field. Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), perimeter strips, or in-field strips. If perimeter strips are implemented, the strips must be at least 4 consecutive rows wide. The corn borer refuge can be treated with a soil-applied or seed-applied insecticide for corn rootworm larval control or a non-Bt foliar-applied insecticide for corn borer control if pest pressure reaches an economic threshold for damage. Growers who fail to comply with the IRM requirements risk losing access to Monsanto corn PIP products.

b) Grower Agreements for MON 89034.

- i. Persons purchasing the Bt corn product must sign a grower agreement. The term "grower agreement" refers to any grower purchase contract, license agreement, or similar legal document.
- ii. The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.

- iii. The registrant must integrate this registration into the current system used for their other Bt corn PIPS to reasonably likely to assure that persons purchasing the Bt corn product will affirm annually that they are contractually bound to comply with the requirements of the IRM program. A description must be submitted to EPA by August 1, 2008.
- iv. The registrant must use grower agreements and submit to EPA within 90 days from the date of registration a copy of that agreement and any specific stewardship documents referenced in the grower agreement. If Monsanto wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty days prior to implementing a proposed change, the registrant must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of the amendment.
- v. The registrant must integrate this registration into the current system to assure that persons purchasing the Bt corn sign grower agreement(s), and must provide within 90 days from the date of the registration a written description of that system. A description must be submitted to EPA by August 1, 2008.
- vi. The registrant shall maintain records of all Bt corn grower agreements for a period of three years from December 31st of the year in which the agreement was signed.
- vii. Beginning on January 31, 2010 and annually thereafter, the registrant shall provide EPA with a report showing the number of units of its Bt MON 89034 corn seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of the twelve month period covering the prior August through July.
- viii. The registrant must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license number, will be protected.

c) IRM Education and IRM Compliance Monitoring Programs for MON 89034.

- i. Monsanto must design and implement a comprehensive, ongoing IRM education program designed to convey to Bt MON 89034 corn users the importance of complying with the IRM program. The program shall include information encouraging Bt MON 89034 corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to Bt MON 89034 corn fields. The education program shall involve the use of multiple media, e.g. face-to-face meetings, mailing written materials, EPA reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by Internet, radio, or television commercials. Copies of the materials will be provided to EPA for its records. The program shall involve at least one written communication annually to each Bt MON 89034 corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Monsanto shall coordinate its education programs with educational efforts of other registrants and other

organizations, such as the National Corn Growers Association and state extension programs.

- ii. Annually, the registrant shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required under paragraph vi. and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.
- iii. On January 31, 2010, the registrant must provide a report to EPA summarizing the activities carried out under the education program for the prior year. Annually thereafter, the registrant must provide EPA any substantive changes to its grower education activities as part of the overall IRM compliance assurance program report. The required features of the compliance assurance program are described in paragraphs iv.-xv.) below.
- iv. The registrant must design and implement an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing its MON 89034 Bt corn product are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to the MON 89034 Bt corn product. The registrant shall coordinate with other Bt corn registrants in designing and implementing its compliance assurance program and integrate this registration into the current compliance assurance program used for their other Bt corn PIPS. The registrant must prepare and submit within 90 days of the date of registration a written description of their compliance assurance program. Other required features of the program are described in paragraphs v. – xv.) below.
- v. The registrant must establish and publicize a “phased compliance approach,” i.e., a guidance document that indicates how the registrant will address instances of noncompliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers. The options shall include withdrawal of the right to purchase Bt corn for an individual grower or for all growers in a specific region. An individual grower found to be significantly out of compliance two years in a row would be denied sales of the Monsanto corn PIP products the next year. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell Monsanto corn PIP products.
- vi. The IRM compliance assurance program shall include an annual survey of a statistically representative sample of Bt corn growers conducted by an independent third party. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. The sample size and geographical resolution may be adjusted annually, based upon input from the independent marketing research firm and academic scientists, to allow analysis of compliance behavior within regions or between regions. The sample size must provide a reasonable sensitivity for comparing results across the U.S. The survey will include only growers planting at least 200 acres of corn in the Corn Belt or 100 acres of corn in corn/cotton growing regions.

- vii. The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of the survey results must include the reasons, extent, and potential biological significance of any implementation deviations.
- viii. The survey shall be designed to obtain grower feedback on the usefulness of specific educational tools and initiatives.
- ix. The registrant shall provide a final written summary of the results of the prior year's survey (together with a description of the regions, the methodology used, and the supporting data) to EPA by January 31 of each year. The registrant shall confer with EPA on the design and content of the survey prior to its implementation.
- x. Annually, the registrant shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey required under paragraphs vi. through viii. and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. The registrant must confer with the Agency prior to adopting any changes to a previously approved CAP.
- xi. The registrant shall train its representatives who make on-farm visits with MON89034 Bt corn growers to perform assessments of compliance with IRM requirements. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, the registrant shall take appropriate action, consistent with its "phased compliance approach," to promote compliance. This on-farm assessment program has no minimum acreage threshold for growers.
- xii. The registrant shall carry out a program for investigating legitimate "tips and complaints" that its growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, the registrant shall take appropriate action, consistent with its "phased compliance approach."
- xiii. If a grower, who purchases MON 89034 Bt corn for planting, was specifically identified as not being in compliance during the previous year, the registrant shall visit with the grower and evaluate whether that the grower is in compliance with the IRM program for the current year.
- xiv. Beginning January 31, 2010 and annually thereafter, Monsanto shall provide a report to EPA summarizing the activities carried out under their compliance assurance program for the prior year and the plans for the compliance assurance program during the current year. The report will include information regarding grower interactions (including, but not limited to, on-farm visits, verified tips and complaints, grower meetings and letters), the extent of non-compliance, corrective measures to address the non-compliance, and any follow-up actions taken.
- xv. The registrant and the seed corn dealers for the registrant must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including the names, personal information, and grower license number of the growers will be protected.

d) Insect Resistance Monitoring for MON 89034.

The Agency is imposing the following conditions for this product:

- i. Post-commercial resistance monitoring programs must be established as an extension of existing programs to track the susceptibility of the key lepidopteran corn pests to the Cry1A.105 and Cry2Ab2 proteins. For the Cry1.A.105 and Cry2Ab2 proteins, the registrant will monitor for resistance and/or trends in increased tolerance for European corn borer, Southwestern corn borer, and corn earworm. Sampling should be focused in those areas in which there is the highest risk of resistance development. Monitoring must be carried out under the same protocols used for the products containing MON 810. Sampling should be focused in those areas in which there is the highest risk of resistance development. In the monitoring program, insect populations will be collected and each protein will be tested separately, rather than a mixture of the two proteins, because resistance to one protein could be masked by the activity of the other.
- ii. In addition to monitoring ECB, SWCB, and CEW, Monsanto will develop and ensure the implementation for resistance monitoring for *Spodoptera frugiperda* (fall armyworm of FAW) in counties which MON 89034 / MON 89034 x MON 88017 sweet corn acreage exceeds 5,000 acres and the pest is capable of overwintering in that county. The registrant should consult with academic and USDA experts in developing the monitoring plan and will provide EPA with a copy of its proposed resistance monitoring plan for EPA's approval prior to implementation. This proposed FAW monitoring plan must be submitted to EPA by January 31 of the year following that in which MON 89034/ MON 89034 x MON 88017 sweet corn acreage exceeds the trigger specified in this requirement (i.e., greater than 5,000 acres in any county in which FAW overwinters). The proposed plan must be implemented the season following the acreage trigger being met. The proposed plan will remain in place until an EPA approved plan can be implemented.
- iii. The registrant must follow-up on grower, extension specialist or consultant reports of unexpected damage or control failures for corn rootworm.
- iv. The registrant must provide EPA with an annual resistance monitoring report by August 31st of each year beginning with 2010, reporting on populations collected the previous year.

e) Remedial Action Plans for MON 89034

The October 15, 2001 Remedial Action Plan for Responding to Resistance in European Corn Borer, Corn Earworm and/or Southwestern Corn Borer must be used for suspected and confirmed resistance of these pests.

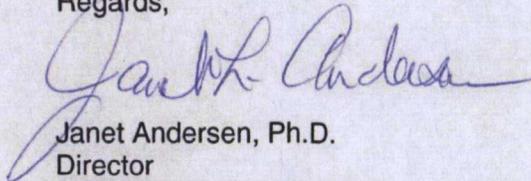
The annual reporting requirements are as follows:

- i. Annual Sales: reported and summed by state (county level data available by request), January 31st each year;

- ii. Grower Agreement: number of units of *Bt* corn seeds shipped or sold and not returned, and the number of such units that were sold to persons who have signed grower agreements, January 31st each year;
- iii. Grower Education: substantive changes to education program completed previous year, January 31st each year;
- iv. Compliance Assurance Plan: Compliance Assurance Program activities and results, January 31st each year;
- v. Compliance: to include annual survey results and plans for the next year; full report January 31st each year;
- vi. Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, August 31st each year.

A stamped copy of the label is enclosed for your records.

Regards,



Janet Andersen, Ph.D.
Director
Biopesticides and Pollution
Prevention Division

Plant-Incorporated Protectant Label

MON 89034

Lepidopteran-Protected Corn
(OECD Unique Identifier: MON-89034-3)

Active Ingredients:

Bacillus thuringiensis Cry1A.105 protein and the genetic material necessary for its production (vector PV-ZMIR245) in event MON 89034 corn (OECD Unique Identifier: MON-89034-3).....0.002-0.0056%

Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary for its production (vector PV-ZMIR245) in event MON 89034 corn (OECD Unique Identifier: MON-89034-3).....0.0015-0.0055%

Percentage (wt/wt) on a dry weight basis whole plant (forage)

Caution

KEEP OUT OF REACH OF CHILDREN

NET CONTENTS _____

EPA Registration No. 524-575

EPA Establishment No. 524-MO-002

Monsanto Company
800 North Lindbergh Blvd.
St Louis, MO 63167

ACCEPTED

JUN 1 0 2008

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for
the pesticide registered under
EPA Reg. No. 524-575

DIRECTIONS FOR USE

It is a violation of Federal law to use this seed in any manner inconsistent with this labeling. Information regarding commercial production must be included in the Technology Use Guide.

MON 89034 can be used to protect corn plants from leaf, stalk, and ear damage caused by corn borers.

MON 89034 can be crossed with MON 88017 for breeding purposes to produce MON 89034 x MON 88017

In order to minimize the risk of these pests developing resistance to MON 89034 corn, an insect resistance management plan must be implemented which includes planting of a structured refuge.

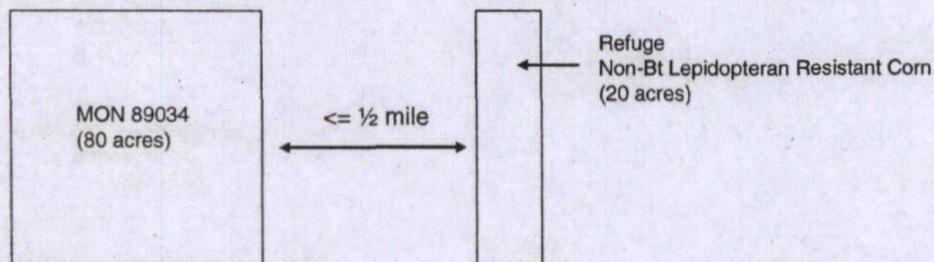
These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn and small scale research trials for observation, nor to commercial hybrid sweet corn.

For MON 89034 sweet corn, growers are required to destroy any MON 89034 sweet corn stalks that remain in the field following harvest via rotary mowing, discing, or plow-down within one (1) month of harvest.

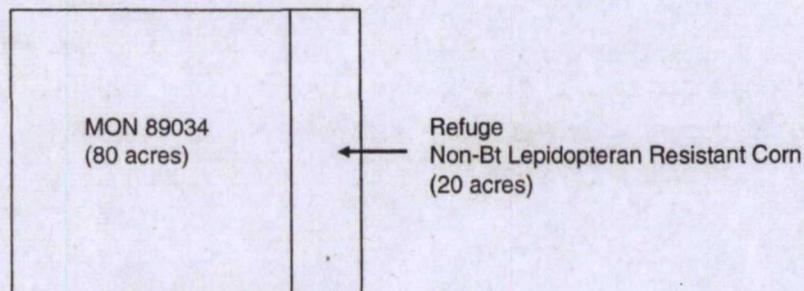
For MON 89034 field corn, grower guides must specify that growers must adhere to the following refuge requirements. Growers must plant a structured refuge of at least 20% corn which is not a lepidopteran-protected Bt corn. Growers who fail to comply with the IRM requirements risk losing access to Monsanto corn PIP products.

Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), and strips across the field.

External refuges must be planted within 1/2 mile.



When planting the refuge in strips across the field, refuges must be at least 4 rows wide.



Insecticide treatments for control of European corn borer, corn earworm, and Southwestern corn borer, cornstalk borer, sugarcane borer, fall armyworm and stalk borer may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). Instructions to growers will specify that microbial Bt insecticides must not be applied to non-Bt corn refuges.

Corn Insects Controlled

European corn borer	<i>Ostrinia nubilalis</i>
Southwestern corn borer	<i>Diatraea grandiosella</i>
Southern cornstalk borer	<i>Diatraea crambidoides</i>
Corn earworm	<i>Helicoverpa zea</i>
Fall armyworm	<i>Spodoptera frugiperda</i>
Corn stalk borer	<i>Papaipema nebris</i>
Sugarcane borer	<i>Diatraea saccharalis</i>

Sales of corn hybrids that contain Monsanto's Bt corn plant-incorporated protectant must be accompanied by a Grower Guide which includes information on planting, production and insect resistance management and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the Bt proteins is planted.

MON 89034 is a product of Monsanto's research program offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5023179, 5110732, 5164316, 5196525, 5322938, 5352605, 5359142, 5378619, 5424412, 6018100, 6051753, 6331665, 6489542, 6645497, 6962705, 7064249, and 7250501.